DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administra

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2953307

August 1, 2003

Hua Ngo, President
H&N Foods International, Inc.
125 Bayshore Blvd.
San Francisco, California 94124

WARNING LETTER

Dear Mr. Ngo:

On March 20, 23, and 24, 2003, we inspected your seafood processing facility, located at Pier 45, Shed D-1, San Francisco, CA. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) – Fish and Fishery Products. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products **adulterated** within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your tuna and Mahi Mahi are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (c) (1). A food safety hazard is defined in 21 CFR 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for **All Scombroid fish** does not list the food safety hazard of pathogen survival through temperature abuse. Your firm receives, stores, and processes tuna that is intended to be consumed as a ready-to-eat (raw as sashimi) product. Firms that produce ready-to-eat products must control pathogen growth through proper refrigeration at receiving, during processing and during storage.

2. You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of noting the adequacy of cooling media at the receiving critical control point to control the Scombrotoxin formation. For example, on March 23, 2003, one shipment of Mahi Mahi from [redacted] and [redacted] shipments of tuna from [redacted] were placed directly into the cooler without being subjected to the monitoring procedures listed in the receiving critical control point. Only when FDA investigators related the incident to management did the firm's employees remove the [redacted] shipments from the refrigerator to conduct their normal monitoring procedures. In addition, the FDA investigator observed the falsification of records on [redacted] tuna shipments from [redacted]. The receiving personnel recorded "yes" on receiving monitoring records for the "Adequacy of cooling media" and "Are cooling medias conditions OK", even though the gel packs were mostly thawed out and the dry ice was completely sublimated.

3. You must take corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). 21 CFR123.7(b)(2) requires that a corrective action ensure that the cause of the deviation is corrected. However, your corrective action plan for Scombroid Fish at the receiving critical control point to control Scombrotoxin formation does not address correcting the cause of the deviation. The receipt of the [redacted] shipments of tuna received from [redacted] on March 23, with thawed gel packs and completely sublimated dry ice, should have prompted communication with the supplier to insure that future shipments would include adequate refrigeration.

4. You must take corrective actions when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). 21 CFR 123.7(b)(1) requires that a corrective action ensures that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation. However, your firm took a corrective action when the temperatures of the [redacted] shipments of tuna deviated from your critical limits at the receiving critical control point that was not adequate to control Scombrotoxin formation. When your employees found that the internal temperatures of fish from the [redacted] cartons and [redacted] cartons of fresh Yellowfin tuna from [redacted] exceeded 40°F at the receiving critical control point, they sampled only [redacted] fish per lot for histamine analysis instead of [redacted] fish per ton, as prescribed in your HACCP plan.

5. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments and the exclusion of pests, with sufficient frequency to ensure control, as evidenced by:

   a. Your firm was using a white plastic container as an ice scoop and was storing the container upside down on a guard pole. The inside of the container was in

direct contact with the top of the guard pole which was contaminated with dark, yellow colored debris.

b. Misuse of shovels that were color coded to avoid contaminating ice. Your firm's ice shovels are white and the shovels used in the cleaning operation are red. The investigator reported a red shovel being used in an ice bin and mentioned the possibility for cross contamination to your firm's management.

c. The investigator reported a 1 ½ to 2 inch gap between the bottom of the roll-up door at the back of your firm's processing facility. This building defect inhibits your firm's ability to exclude pests from the food plant

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulations, and the Current Good Manufacturing Practice regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Please send your reply to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Charles D. Moss, Acting DD

for Dennis K. Linsley
District Director
San Francisco District

Enclosure:
Form FDA 483

cc: Jesse T. Hiraki, Manager